II. REMARKS

A. Status of the claims

Claim 20 has been amended to correct a typographical error.

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-55 are pending, and are encompassed by the elected invention (including the elected species).

B. Rejection under 35 U.S.C. § 103

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-55 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 4,910,205 to Kogan et al. ("the Kogan reference"), purportedly "in view of applicants' admission in paragraph 0123 and U.S. Patent No. 5,968,547 to Reder et al." *Office Action, page 3.*

This rejection is respectfully traversed.

1. It is improper to use the present specification as an "instruction manual or 'template' to piece together teachings of prior art" to arrive at the claimed invention

Applicants respectfully submit that the rejection is improper, because it uses the present specification as an "instruction manual or 'template' to piece together teachings of prior art" to arrive at the claimed invention.

"It is impermissible to use claimed invention as instruction manual or 'template' to piece together teachings of prior art so that the claimed invention is rendered obvious and unpatentable." *In re John R. Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). "To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction—an illogical and inappropriate process by which to determine patentability." *Sensonics,*

Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570 (Fed. Cir. 1983) (citing *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)). "The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made." *Id.* (citing *Interconnect Planning Corp. v. Feil,* 774 F.2d 1132, 1138 (Fed. Cir. 1985)).

In the present rejection, the Examiner acknowledged on page 5 of the Office Action that the Kogan reference "does not teach the specific delivery profile of loratadine," and did not contend that the Reder reference (which does not mention loratadine) describes the "desired pharmacokinetic" parameters of loratadine. In making the rejection, the Examiner relied on the present specification (i.e., the paragraph bridging page 23 and 24, describing the calculations of the dosing rate suggested by the Applicants, and the first full paragraph on page 24, stating that "[a]ny type of transdermal delivery system may be used in accordance with the methods of the present invention so long as **the desired** pharmacokinetic and pharmacodynamic response[s] are attained") and used this disclosure to combine the cited references and assert that the cited references render the present claims obvious.

Applicants respectfully submit that, as purportedly admitted by the Examiner, the "**desired** pharmacokinetic" parameters of loratadine are not described in the cited references. The cited references also do not show how to calculate the claimed mean relative release rates of loratadine from the data regarding the bioavailabity of loratadine. Moreover, there is nothing in the cited references that links the presently claimed plasma level of loratadine at steady state with the presently claimed mean relative release rates of loratadine at three different time points (24, 48 and 72 hours). The cited references therefore cannot provide a reason for one of ordinary skill in the art to formulate and use loratadine transdermal delivery systems as recited in the present claims.

Applicants respectfully submit that it is only through the impermissible use of the information learned from the present specification that the Examiner is able to combine the cited references and assert that the present claims are rendered obvious by the

combination of the cited references. Accordingly, Applicants submit that the Examiner has impermissibly used the present specification as an "instruction manual or 'template' to piece together teachings of prior art" to arrive at the claimed invention.

For this reason, Applicants submit that the rejection is improper and should be withdrawn.

2. The claimed steady state plasma level of loratadine cannot be expected from the cited references

In making the rejection, the Examiner contended, on page 4 of the Office Action, that the claimed "plasma level of loratadine of the prior [art] is expected to be same as those disclosed by the prior art ...." *Office Action*, page 4.

Applicants respectfully disagree. As explained in the responses filed on February 17, 2009, and September 15, 2009, the steady state plasma level of loratadine calculated from the data provided in the Kogan reference using the available pharmacokinetic information about loratadine is different from the steady state plasma level of loratadine recited in the present claims. Accordingly, the claimed steady state plasma level of loratadine cannot be expected from the Kogan reference. As there is no mention of any loratadine formulations in the Reder reference, the claimed steady state loratadine concentration also cannot be expected from the Reder reference.

Accordingly, the claimed steady state plasma level of loratadine cannot be expected from the combination of the Kogan reference and the Reder reference.

3. The claimed release profile of loratadine is not suggested by the cited references

Applicants submit that the claimed steady state plasma level of loratadine is not taught or suggested by the cited references for the reasons given above. The Examiner has acknowledged on page 5 of the Office Action that the Kogan reference "does not

teach the specific delivery profile of loratadine," and did not contend that the claimed delivery profile of loratadine is disclosed in the Reder reference, which does not even mention loratadine.

As stated above, the claimed steady state plasma level of loratadine is not taught or suggested by the cited references. The only connection between the presently claimed plasma level of loratadine at steady state with the presently claimed mean relative release rates of loratadine at three different time points (24, 48 and 72 hours) is in the present specification, rather than in the cited references. The cited references therefore cannot teach or suggest the claimed release profile of loratadine (a combination of (i) the claimed steady state plasma level of loratadine and (ii) the presently claimed mean relative release rates of loratadine at three different time points (24, 48 and 72 hours)).

In response to the Examiner's statement on page 8 of the Office Action, that "the device having the same drug formulation and formulation for delivering the drug as taught by the combination of the cited references is expected provide the same delivery rates and plasma concentrations as those disclosed by the prior art in combination since the combined teachings of the prior art teaches the same drug in the same formulation," Applicants respectfully submit that the combination of the cited references does not teach the same drug in the same formulation. Applicants respectfully reiterate that there is no description in the cited references of a loratadine transdermal device having the composition recited in the present claims and providing the claimed plasma level of loratadine at steady state and mean relative release rates at three different time points. Accordingly, Applicants submit that it is inappropriate to conclude that the devices of the cited references will necessarily provide the presently claimed release profile of loratadine.

For the foregoing reasons, and the reasons presented in the response filed on September 15, 2009, hereby incorporated by reference, withdrawal of the rejection is respectfully requested.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully invited to contact the undersigned by telephone, if a telephone interview would advance prosecution of the present application.

Respectfully submitted,
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